

OCT 28 2004

**510(k) SUMMARY**

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

**510(k) SUMMARY
for
AQuify Multipurpose Solution**

1. **Submitter Information**
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person: Steven Dowdley
Telephone No. 678-415-3897
2. **Proprietary Name:** **AQuify Multipurpose Solution**
Classification Name: Soft (hydrophilic) Contact Lens Solution
3. **Predicate Device(s)**
KARATS Multipurpose Solution (for lenses replaced in less than 30 days)
ReNu Multipurpose Solution
Complete Comfort Plus Multipurpose Solution
Opti-Free Express Multipurpose Solution
4. **Description of the Device**
AQuify Multi-Purpose Solution is a sterile aqueous solution containing dexpanthenol, preserved with polyhexanide 0.0001%, pluronic F127, edetate disodium dehydrate, sorbitol, tromethamine, sodium phosphate dihydrogen, and purified water.
5. **Indications for Use**
AQuify Multipurpose Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting and storing soft (hydrophilic) lenses (including silicone hydrogel lenses) as recommended by your eye care practitioner. AQuify Multipurpose Solution is also indicated for daily protein removal when used with the no rub directions for use.
6. **Description of Safety and Substantial Equivalence**

Cleaning Studies
Previous studies have demonstrated the cleaning capacity of AQuify Multipurpose Solution with soft contact lenses. The study previously submitted and reviewed under K021635 demonstrated that AQuify MPS is substantially equivalent in terms of daily protein removal.

Dehydration Effect
Using a dynamic vapor sorption system, lenses treated with AQuify Multipurpose Solution showed an effect on the steady state water content at a relative humidity of 50%. AQuify

MPS was statistically better than control lens multipurpose solution tested at increasing the steady-state water content within a lens group. All groups of lenses indicate that AQUIFY had a higher water content after 60 minutes at a relative humidity of 50%. This demonstrates that AQUIFY increased the water holding capabilities of the hydrogel lenses tested.

Microbiology

A series studies were also completed to demonstrate the microbiological efficacy of AQUIFY Multipurpose Solution. These studies were submitted and reviewed under K021635. These studies demonstrate that AQUIFY Multipurpose Solution meets the stand-alone criteria of the disinfection efficacy test of the FDA May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products. The product also meets the USP Modified criteria for Preservative Effective Testing and USP Sterility Test requirements.

Toxicology

A series toxicology studies were completed, submitted and reviewed under K021635.

Clinical Evaluation

The trial was a three-month prospective, randomized, single masked trial consisting of baseline, two-week, one-month and final three-month visits. Subjects compared the AQUIFY Multipurpose Solution and ReNu Multipurpose Solution on a contra-lateral basis. Study participants were all randomized for which eye used the test and which eye used the control product.

The primary objective of this clinical trial was to evaluate safety, efficacy, and preference between AQUIFY Multipurpose Solution and ReNu MultiPlus Multipurpose Solution. Both solutions used a pre-rinse and a minimum 4 hour to overnight soak.

Symptoms

There were no significant differences in the AQUIFY Multipurpose Solution and control solution with regards to symptoms.

Efficacy at Two Weeks

Statistically significant differences in favor of AQUIFY MPS were found for overall comfort and particularly overall dryness and overall lens awareness 1-10 scores and for lens awareness preference at the two-week visit. There were also strong trends that were almost statistically significant for overall comfort and lens awareness in favor of AQUIFY MPS.

Efficacy at One Month

Statistically significant differences in favor of AQUIFY MPS were found for overall comfort and dryness 1-10 scores and for overall comfort, dryness, and lens awareness preferences.

Efficacy at 3 Months

Statistically significant differences in favor of AQUIFY MPS were found for insertion and overall comfort 1-10 scores and for insertion comfort, overall comfort, dryness, and lens awareness preferences.

Efficacy Conclusions

Overall comfort 1-10 scores and preferences were consistently statistically significantly better with AQUIFY MPS over ReNu Multiplus throughout the trial. AQUIFY MPS was also statistically significantly preferred for less dryness throughout the trial having higher mean 1-10 scores for all subjective categories for all visits over ReNu Multiplus. AQUIFY

MPS was increasingly preferred as the trial progressed to almost a 4:1 ratio (42% versus 11%) by the final visit with over 50% of the subjects expressing a preference.

Dark Field Image Analysis

With regards to dark field image analysis, there were no statistically significant differences in the investigator appraisal of lens deposits, front surface wetting and objective dark-field image analysis of lenses worn for 90 days. Both the test and control product provided clinically acceptable lens cleanliness when used according to their directions for use as measured by dark field image analysis of the returned lenses.

7. Conclusion Drawn from Data Supporting Equivalence Determination:

We conclude that **AQUIFY Multipurpose Solution** is substantially equivalent to ReNu Multiplus Multipurpose Solution when used to clean, rinse, chemical (not heat) disinfect and store soft (hydrophilic) contact lenses on a conventional replacement schedule of three months or longer



OCT 28 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CIBA Vision Corporation
c/o Mr. Steven Dowdley
11460 Johns Creek Parkway
Duluth, Georgia 30097

Re: K031753
Trade/Device Name: AQuify Multipurpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Solution
Regulatory Class: Class II
Product Code: LPN
Dated: September 7, 2004
Received: September 8, 2004

Dear Mr. Dowdley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2- Mr. Steven Dowdley

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink that reads "A. Ralph Rosenthal". The signature is fluid and cursive, with the first name "A." and last name "Rosenthal" clearly legible.

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K031753

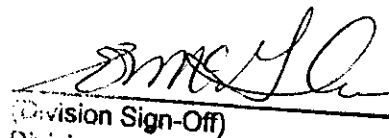
Device Name: AQuify Multi-Purpose Solution

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☐ or over-the-counter: ☒



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K031753